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First-In-Man IVUS Findings of the Prohealing PROTEX™ Coronary Stent System for the Treatment of Coronary Artery Disease

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Background: The PROTEX system integrates a cobalt alloy stent platform with prohealing extracellular matrix coating that facilitates rapid coverage of the stent surface by endothelial cells from the tissue and/or endothelial progenitor cells in the blood stream. This study aimed to evaluate vessel response to this novel device in human coronary lesions as assessed by IVUS.
Methods: In a first-in-man, prospective, multicenter, single-arm trial of PROTEX, serial (baseline and 6 months) IVUS was performed in 38 patients. In addition to the standard IVUS variables, a neointima-free frame ratio (number of frames without neointima/total frame number) was calculated to assess gross coverage of struts. Cross-sectional (cross-sectional narrowing: CSN) and longitudinal severity indices (% stent length with CSN >60%: IH60) of lumen encroachment by neointima were also assessed.
Results: Overall, vessel behind the stent showed a slight shrinkage during follow-up, and no case had excessive positive remodeling or late-acquired incomplete stent apposition. The neointima-free frame ratio was 1.4%, indicating almost no exposed stent struts at 6 months. In cases with significant lumen encroachment (max CSN >60%), the longitudinal severity index was 13.4%, representing focal neointimal accumulation.

	Post-procedure	6 months follow-up	p
Vessel volume (mm^3/mm)	15.3 ± 4.0	14.7 ± 3.5	0.0252
Lumen volume (mm^3/mm)	7.8 ± 1.6	5.4 ± 1.6	<0.0001
Neointimal obstruction (%)	-	28.2 ± 12.6	-
Max CSN (%)	-	45.4 ± 16.4	-
Cases with Max CSN >60% (%)	-	21.6	-
IH60 in Cases with Max CSN >60%	-	13.4 ± 16.4	-
Neointima-free frame ratio	-	1.4 ± 7.9	-
Edge Dissection (%)	6.6	0	-
Late ISA (%)	-	0	-

IH60 was defined as percent stent length with CSN >60%

CSN; cross sectional narrowing, ISA; incomplete stent apposition

Conclusion: First-in-man IVUS results of PROTEX demonstrated favorable vessel responses with nearly complete tissue coverage of struts within 6 months. Possible synergy of this prohealing stent coating and antiproliferative agents may warrant investigations.

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Vascular Healing After Endothelial Progenitor Cell Capturing Stent Implantation at 30 days

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Background: As an alternative to DES, a novel antibody-coated endothelial progenitor cell capturing (EPC) Genous (OrbusNeich Medical GmbH, Wiesbaden, Germany) stent has been developed, which has shown good results in unselected patiens. The capture of circulating endothelial progenitor cells promotes rapid endothelialization of the stent, which in turn allows shorter duration of dual-antiplatelet treatment. Optical coherence tomography (OCT) has become the method of choice for evaluating stent endothelialization and vascular healing.
Methods: We analyzed the percentage of stent strut endothelial cell coverage (binary strut coverage) and stent apposition using optical coherence tomography (OCT) and assessed the reactivity of the microcirculation using coronary flow reserve (CFR) by transthoracic echocardiography after implantation of EPC stents. A total of 20 patients with a lesion in LAD were enrolled and OCT and CFR were performed at 30 days after stent implantation.
Results: The binary stent strut coverage was 94.8 %. No thrombi were detected and the percentage of malapposed stent struts was 2.4 %. The mean NIH thickness was 108 ± 96 μm and NIH% 8.9 ± 7.4 %. Mean CFR was 2.5 ± 0.2. Two patients had abnormal CFR < 2.0 (1 restenosis and 1 de novo lesion in the target vessel).

Table. Optical tomographic measurements

Follow-up, 30 days	GENOUS (n=20)
No. of Cross Sections	336
No. of Struts	3260
Mean Lumen Area (mm2)	7.02 ± 1.51
Mean Stent Area (mm2)	7.57 ± 1.60
Mean NIH Thickness (μm)	107.9 ± 96.4
Mean NIH area (%)	8.9 ± 7.4
Binary Strut Coverage, (%)	94.8 %
Presence of Thrombi, n (%)	0 %

Conclusion: Evaluated with OCT and CFR, the Genous stent showed favorable healing properties with rapid endothelialization, low NIH% area, few malapposed struts and adequate vasodilation response at 30 days excluding patient with restenosis.

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Evaluation of Neointimal Healing of EPC-Capturing Sirolimus-Eluting COMBO Stent by Optical Coherence Tomography: The EGO-COMBO Pilot Study (interim results)

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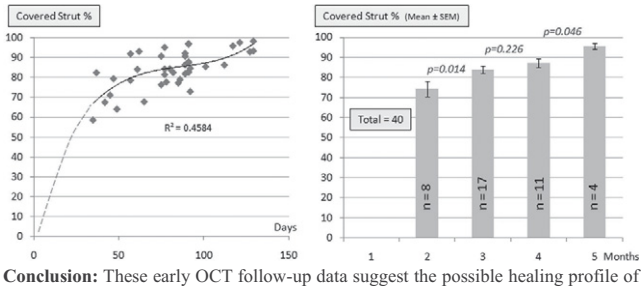
Background: COMBO Stent (OrbusNeich Medical, FL, USA) is a hybrid version of the endothelial progenitor cell (EPC) capturing GENOUS Stent, with an additional abluminal 5 μg/mm sirolimus coating, about ½ the dose of current sirolimus-eluting stent but with a similar release profile (about 90% of the drug released by 35 days) via a Surmodics SynBiosys™ bio-degradable polymer, aiming at optimal neointimal suppression similar to other DES while retaining the EPC capturing benefit (envisaged better endothelialization and less late stent thrombosis) as reported in animal models. Such combined benefits were evaluated clinically in this Study.
Methods: In this prospective, single center, pilot study, 60 patients treated by COMBO Stent were randomised to 4 monthly groups (in 1:2:2:1 ratio). OCT was performed sequentially at baseline post-stenting, at early follow-ups in 4 groups at 2nd, 3rd, 4th, and 5th month (for early neointimal healing), and at 9 months (for OCT late loss). Independent OCT core laboratory performed the covered strut % and neointima analyses, while in-house analyses further stratified the early strut coverage into 6 categories.
Results: To date, all 60 patients (30% diabetic, 87 COMBO stents implanted) were enrolled; 40 had the first OCT follow up. A total of 7004 frames and 60069 struts were analyzed. The mean percentage of covered struts (with proper apposition) was 74.4%, 84.0%, 87.4% & 95.6%, p=0.014, 0.226, & 0.046, from 2nd to 5th monthly group, respectively (refer to Figure). No MACE was recorded. Study Limitations: (1) no other DES control arm & (2) OCT classification of early strut coverage requires further validation.



Conclusion: These early OCT follow-up data suggest the possible healing profile of the new EPC-capturing COMBO DES, with near 100% strut coverage by 140 days. Nine months follow-up data are pending. Clinical data on larger patient population are needed to verify these promising imaging results.

TCT-236

Twelve-Month Clinical Efficacy and Safety of Zotarolimus- versus Everolimus-Eluting Stents in a Series of Asian Population

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Background: Recently, newer generation drug-eluting stents (DESs) have been widely used with improved performance and safety. However, there have been limited data comparing angiographic and clinical outcomes of individual newer generation DESs in real world clinical practice, specifically in Asian population.
Methods: A total of 608 patients (pts) underwent percutaneous coronary intervention (PCI) with Zotarolimus-eluting stents (ZES group; Endeavor ResoluteTM, n=238 pts) and Everolimus-eluting stents (EES group; PromusTM or XienceTM n=370 pts) were enrolled for this study. Angiographic outcomes at 6 months and major clinical outcomes up to 12 months were compared.
Results: There were no significant differences in baseline clinical characteristics between the two groups. At 6 months, angiographic outcomes were similar between the two groups. At 12 months, there was a trend toward higher incidence of non-target lesion revascularization (TLR) target vessel revascularization (TVR) in the EES group; however other major clinical outcomes including mortality, Q-wave myocardial infarction (MI), repeat PCI and major adverse cardiac events (MACEs) were similar between the two groups up to 12 months (Table)

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Table: Six-month Angiographic and 1-year Clinical Outcomes

Variables, N (%)	ZES group (n=238 pts)	EES group (n=370 pts)	p-value
Angiographic Outcomes at 6 months			
Mean DS%	19.4±17.6	17.9±14.6	0.270
Follow up MLD (mm)	2.28±0.61	2.31±0.51	0.328
Late Loss (mm)	0.30±0.44	0.30±0.43	0.735
Clinical Outcomes at 12 months			
Total Death	9 (4.0)	11 (3.2)	0.611
Cardiac Death	8 (3.6)	11 (3.2)	0.816
Non-cardiac Death	1 (0.4)	0 (0.0)	0.216
Repeat PCI	11 (4.9)	18 (5.3)	0.856
TLR	6 (2.7)	12 (3.5)	0.584
TVR	6 (2.7)	15 (4.4)	0.295
Non-TLR TVR	0 (0.0)	5 (1.5)	0.069
Non TVR	5 (2.2)	3 (0.9)	0.181
All MACE	20 (9.0)	28 (8.2)	0.753
Stent thrombosis	2 (0.9)	3 (0.9)	0.983

Conclusion: In our study, both new generation DESs, ZES and EES were similarly effective and safe up to 1 year following routine PCI in Asian population

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Two-Year Outcomes of a Propensity-Matched Comparison of the ION and TAXUS Liberté Paclitaxel-Eluting Stents

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Background: The TAXUS Element (ION) paclitaxel-eluting stent (PES) uses the same polymer and drug as the TAXUS Liberté PES, but with a novel thin (81μM) strut platinum chromium metal alloy cell design. We present 2-year data comparing clinical outcomes between the ION and TAXUS Liberté PES.
Methods: Patient-level data from 2298 subjects treated with PES were pooled from the TAXUS ATLAS (TAXUS Liberté Stent) and PERSEUS (ION Stent) trials and propensity matched 1:1 to adjust for significant baseline differences.
Results: Two-year MACE was significantly lower in the ION versus the TAXUS Liberté group, with and without propensity matching (Table), driven largely by a reduction in non-Q-wave MI. Numerical reductions in non-Q-wave MI were seen in both the periprocedural (2.1% vs. 1.3%, P=0.12 unadjusted; 2.4% vs. 0.8%, P=0.02 matched) and discharge – 2 year timeframes (1.3% vs. 0.5%, P=0.07 unadjusted; 1.2% vs. 0.6%, P=0.28 matched). Non-Q-wave MI was significantly lower with ION in patients treated with single stents (3.1% vs. 1.4%, P=0.01 unadjusted; 3.4% vs. 1.4%, P=0.02 matched) but not in patients treated with multiple stents, although sample sizes were small (5.9% [N=85] vs. 5.6% [N=90], P=0.94 unadjusted; 7.7% [N=39] vs. 1.8% [N=55], P=0.17 matched). Stent thrombosis (ARC definite/probable) was numerically less frequent following ION use.

Unadjusted	TAXUS Liberté (N=1132)	ION (N=1166)	*P* Value
MACE	15.7% (176)	11.6% (131)	0.003
Cardiac Death	1.8% (20)	1.4% (16)	0.47
Myocardial Infarction	4.4% (49)	2.5% (29)	0.02
Q-Wave	1.0% (11)	0.7% (8)	0.46
Non-Q-Wave *	3.4% (38)	1.8% (21)	0.02
TVR	11.8% (131)	9.5% (107)	0.07
TLR	7.6% (85)	5.7% (64)	0.06
Non-TLR	6.1% (68)	5.1% (57)	0.27
TLF	11.1% (125)	7.8% (88)	0.005
All Death	3.0% (34)	1.9% (22)	0.09
Stent Thrombosis †	1.3% (15)	0.6% (7)	0.08
1:1 Propensity Matched	**TAXUS Liberté (N=663)**	**ION (N=663)**	***P* Value**
MACE	15.1% (99)	11.5% (73)	0.04
Cardiac Death	1.8% (12)	1.7% (11)	0.87
Myocardial Infarction	4.9% (32)	2.5% (16)	0.02
Q-Wave	1.2% (8)	1.1% (7)	0.81
Non-Q-Wave *	3.6% (24)	1.4% (9)	0.01
TVR	11.0% (72)	9.6% (61)	0.37
TLR	7.2% (47)	6.2% (39)	0.42
Non-TLR	5.4% (35)	4.4% (28)	0.40
TLF	11.0% (72)	8.2% (52)	0.07
All Death	2.9% (19)	2.0% (13)	0.31
Stent Thrombosis †	1.5% (10)	0.8% (5)	0.20

The ION stent is commercialized under the name TAXUS Element Stent outside of the United States.
* De novo elevation of CK Total levels >2.0 x ULN without the presence of new Q-waves. CK-MB must have been positive (if performed).
†Academic Research Consortium (ARC) Definite/Probable
Data presented as % (number of events), based on Kaplan-Meier estimates with a log-rank *P* value.
Abbreviations: MACE: major adverse cardiac events (cardiac death, MI, TVR); MI: myocardial infarction;
TLF: target lesion failure (TLR, target-vessel-related MI, target-vessel-related cardiac death);
TLR: target lesion revascularization; TVR: target vessel revascularization.

Conclusion: In this exploratory post hoc analysis, ION was associated with lower 2-year MACE than TAXUS Liberté, driven mainly by reduced non-Q-wave MI. These differences may be explained by thinner struts and modified cell design in the ION stent, although evolution in adjunctive therapies and stenting technique may also contribute.

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Proximal & Distal Maximal Luminal Diameters (Dmax) as a Guide to Appropriate Deployment of the Everolimus-Eluting Bioresorbable Vascular Scaffold: A Substudy of the ABSORB Cohort B & On-Going ABSORB EXTEND Single Arm Study

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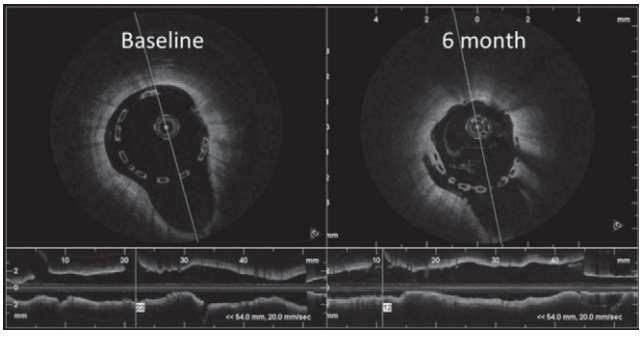
Background: Due to the limited distensibility of the everolimus-eluting bioresorbable vascular scaffold (ABSORB) compared to metallic platform stents, quantitative coronary arteriography (QCA) is a mandatory requirement for ABSORB deployment in ABSORB EXTEND. Visual assessment of vessel size in the ABSORB Cohort B study often lead to under (Fig.) & over-sizing of the 3mm ABSORB in coronary vessels (recommended vessel diameter ≥2.5-≤3.3mm), with an increased risk of spontaneous incomplete scaffold apposition post deployment. We report whether mandatory QCA assessment of vessel size pre-implantation utilising the Dmax & established interpolated reference vessel diameter (RVD) measurements has improved device/vessel sizing.
Methods: Pre-implantation post-hoc QCA analyses of all 101 patients from ABSORB Cohort B (102 lesions) & first consecutive 101 patients (108 lesions) from ABSORB EXTEND were undertaken by an independent corelab; all patients had a 3mm ABSORB implanted. Comparative analyses were performed.
Results: Within ABSORB Cohort B a greater no. of over-sized vessels (>3.3mm) were identified utilizing the Dmax compared to the RVD (17 vessels, 16.7% vs. 3 vessels, 2.9%; p=0.002). Comparative analyses demonstrated a greater no. of appropriate vessel size selection (75 vessels, 69.4% vs. 48 vessels, 47.1%; p=0.001), a trend towards a reduction in implantation in small (<2.5mm) vessels (29 vessels, 26.9% vs. 40 vessels, 39.2%; p=0.057) & a significant decrease in the implantation in large (>3.3 mm) vessels (4 vessels, 3.7% vs. 17 vessels, 16.7%; p=0.002) in ABSORB EXTEND. Bland–Altman plots suggested a good agreement between operator/corelab assessed Dmax measurements.



3mm BVS implanted in vessel with Dmax 4.42mm

Conclusion: The introduction of mandatory Dmax measurements of vessel size prior to ABSORB implantation significantly reduced the undersizing of the 3.0mm ABSORB in large vessels validating the use of this technique in vessel sizing prior to ABSORB implantation.

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FINAL RESULTS OF THE SVELTE TRIAL WITH THE NOVEL ACROBAT BALLOO-EXPANDABLE SOAW CORONARY SYSTEM

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Background: Direct stenting (DS) may potentially reduce vessel trauma, "geographical miss", prevent distal embolization and save time/money during PCI. However, DS is currently performed in < 50%. Among the reasons to pre-dilate, vessel anatomy (tortuosity and amount of calcification) plays a central role in the operator's decision.The Acrobat SOAW (Stent-On-A-Wire) coronary system combines a very-thin (81 μ) balloon-expandable, Cro-Co stent mounted on a delivery system with a 0.012" integrated guidewire tip (distance from the tip of the wire to the stent is 22mm). We sought to determine the efficacy of this novel device.
Methods: SVELTE trial is a multicenter(Brazil, Netherlands and Colombia), prospective, non-randomized, single-arm study of the Acrobat SOAW for the treatment of de novo coronary lesions no longer than 18mm and located in native vessels of 2.5 to 3.5mm. DS was highly recommended. Patients were oriented to stay on dual anti-platelet regimen for at least 1 month. Main exclusion criteria were PCI in the setting